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Bibliographic Data	
Authors	Cherkin DC, Sherman KJ, Kahn J, and et al.
Title	A Comparison of the Effects of 2 Types of Massage and Usual Care on Chronic Low Back Pain: A Randomized, Controlled Trial
PMID	21727288
Citation	Ann Intern Med. 2011 July 5; 155(1): 1–9.
Other information if relevant	TRIAL REGISTRATION – none listed

Methods	
Aim of study	To determine if relaxation massage reduces pain and improves function in patients with chronic low back pain (LBP), and compare the effectiveness of relaxation massage and structural massage.
Design	Single-blind parallel group randomized controlled trial.

Participants	
Population from which participants are drawn	Participants were invited through advertisements in Group Health's integrated health care delivery system plan's magazine and mailings to plan members 20 to 65 years old with outpatient visit diagnoses suggesting non-specific chronic low back pain in Seattle, Washington.
Setting (location and type of facility)	Restricted to a single site in Group Health's integrated health care delivery system in Seattle, Washington. Massage was conducted in therapists' offices.
Age	adults 20 to 65 years of age, mean age 47 years
Sex	144 men, 257 women, total 401 at baseline
Total number of participants for whom outcome data were reported	At the primary endpoint of weeks 381 (95%) had follow-up outcome data, 373 (93%) at 26 weeks, and 365 (91%) at 52 weeks. A total of 401 were analyzed.
Inclusion criteria	Adults between 20 and 65 with back pain lasting at least three months without 2 or more pain-free weeks and pain bothersomeness rated at least 3 on a 0 to 10 scale.
Exclusion criteria	1) specific causes of back pain (e.g., cancer, fractures, spinal stenosis), 2) complicated back problems (e.g., sciatica, prior back surgery in past 3 years, medicolegal issues), 3) conditions making treatment difficult (e.g., paralysis, psychoses), 4) conditions that might confound treatment effects or interpretation of results (e.g., severe fibromyalgia, rheumatoid arthritis), 5) inability to speak English, 6) massage within past year, or 7) plans to visit provider for back pain.
Other information if relevant	There were no significant differences between groups in participants' baseline sociodemographic, clinical characteristics, or outcome measure scores. 75% of participants had LBP for at least one year.

Intervention Groups

Group 1	
Group name	Relaxation massage

Number in group	136 at baseline
Description of intervention	Massage, intended to induce a generalized sense of relaxation, permitted effleurage, petrissage, circular friction, vibration, rocking and jostling, and holding. Therapists were given time parameters for each body region, including 7-20 minutes on back and buttocks
Duration of treatment period	10 weekly treatments, with first visits lasting 75 to 90 minutes and follow-up visits 50 to 60 minutes.
Co-interventions if reported	Up to three home exercises from a pre-defined list of seven exercises recommended by the therapist. A 2.5-minute relaxation exercise CD as home exercise to enhance and prolong treatment benefits was provided.
Additional information if relevant	

Group 2	
Group name	Structural Massage
Number in group	132 at baseline
Description of intervention	Massage focused on correcting and alleviating musculoskeletal contributors and abnormalities to back pain, allowed myofascial, neuromuscular, and other soft tissue techniques. Myofascial techniques were intended to engage and release identified restrictions within myofascial tissues. Neuromuscular techniques were used to resolve soft tissue abnormalities by mobilizing restricted joints, lengthening constricted muscles and fascia, balancing agonist/ antagonist muscles, and reducing hypertonicity. Areas of the body treated varied across patients and treatment sessions.
Duration of treatment period	10 weekly treatments, with first visits lasting 75 to 90 minutes and follow-up visits 50 to 60 minutes.
Co-interventions if reported	Up to three home exercises from a pre-defined list of seven exercises recommended by the therapist. Therapists could recommend a psoas stretch home exercise to enhance and prolong any benefits of structural massage.
Additional information if relevant	

Group 3	
Group name	Usual care, control group
Number in group	133 at baseline
Description of intervention	Received no special care but were paid $50. Actual care was determined from medical records and interviews.
Duration of treatment period	10 weeks
Co-interventions if reported	none
Additional information if relevant	

Co-Primary outcomes	
Outcome name and criteria for definition	Back-related dysfunction and symptoms assessed at 10-weeks, immediately after treatment completion. Dysfunction was measured using the modified Roland Disability Questionnaire (RDQ) and a between group difference in improvement in mean values of at least 2.0 points on this 23 pt. scale was considered clinically meaningful. Symptoms were measured using the Symptom Bothersomeness scale rating their pain during the past week from 0 ("not at all") to 10 ("extremely"). A between-group difference in improvement in mean values of at least 1.5 points was considered clinically meaningful.
Time points measured and/or reported	Baseline (before randomization), after randomization at 10 weeks (primary end point), and at 26 and 52 weeks.
Differences between groups	1) All groups showed improved function and decreased symptoms at 10 weeks. For function, both the structural and relaxation massage groups had clinically meaningful reductions in the RDQ ($\geq$ 3 points) at all 3 time points, but this was not true for the usual care group. At 10 weeks, the structural group decreased 3.6 points, the relaxation group decreased 5.6 points, and the usual care group decreased 1.5 points on the RDQ. For Symptom Bothersomness (SB), both the structural and relaxation massage groups showed clinically meaningful reductions in symptoms on the SB scale ($\geq$ 2 points) at 10 weeks, but not at 26 and 52 weeks. The usual care group showed no clinically meaningful reductions in SB at any time point. On the SB scale at 10 weeks, the structural group decreased 1.8 points, the relaxation group decreased 2.1 points, and the usual care group decreased 0.6 points. 2) Functional improvement was significantly greater and clinically meaningful (difference of $\geq$ 2 pts) in both massage groups when compared to the usual care group at 10 weeks follow-up. Participants in the relaxation massage group improved by 2.9 (95% CI: 1.8, 4.0) more points on the RDQ scale than those in the usual care group, and those in the structural massage group improved by 2.5 (95% CI: 1.4, 3.5) more points than those in the usual care group ($p<0.001$ for both). Even though some statistically significant differences between the massage groups and usual care were present at 26 and 52 weeks for function, clinical meaningful differences between groups did not persist. 3) The nonsignificant difference in function between the two types of massage at 10 weeks was small (adjusted difference 0.5 points (95% CI: -0.5, 1.5; P=0.35)) and clinically unimportant. 4) Symptom improvement was significantly greater and clinically meaningful (difference of $\geq$ 1.5 pts) in both massage groups when compared to the usual care group at 10 weeks follow-up. Participants in the relaxation massage group improved by 1.7 (95% CI: 1.2, 2.2) more points on the SB scale than those in the usual care group, and those in the structural massage group improved by 1.4 (95% CI: 0.8, 1.9) more points than those in the usual care group ($p<0.001$ for both). Statistically significant differences between the massage groups and usual care were not present at 26 and 52 weeks for symptoms. 5) The nonsignificant difference in symptoms between the two types of massage at 10 weeks was small (adjusted difference 0.3 points (95% CI: -0.2, 0.8)) and clinically unimportant.

Differences between groups (continued)	6) For function and symptoms, there were no clinically meaningful differences between types of massage at all 3 follow-up time points. At 10 weeks, 62%-65% of participants experienced clinically meaningful improvement in the massage groups compared with only 38% in the usual care group (adjusted overall P<0.001).
Additional information if relevant	

Secondary outcomes	
Outcome name and criteria for definition	The secondary outcome measures were 1) 26- and 52-week measures of the primary outcomes, 2) percentage of participants with pre-specified clinically meaningful reductions in dysfunction (3+ point decrease on the RDQ scale) and symptoms (2+ point decrease in symptom bothersomeness), 3) physical and mental health Short Form Health Survey 12 component summary scores, 4) self-reported medication use for back pain in prior week, 5) days spent in bed, home from work or school, or cutting down on usual activities due to back problem during past week, 6) global improvement in back-related dysfunction rated on a seven point scale from "completely gone" to "much worse", 7) feelings if spent rest of life with back pain experienced in past week (7-point scale ranging from "delighted" to "terrible"), 8) satisfaction with back care using a 5-point Likert scale (ranging from very satisfied to very dissatisfied), and 9) total costs of back pain-related visits, imaging studies, and medications during follow-up year from electronic medical records.
Time points measured	Baseline (before randomization), after randomization at 10 weeks (primary end point), and at 26 and 52 weeks.
Differences between groups	- At 10 weeks, there were statistically significant differences among the groups for activity limitations (days in bed, reduced activity, days off work), patient global rating of improvement, use of nonsteroidal anti-inflammatory medications, satisfaction with current level of back pain, satisfaction with back pain care, and mental health (Short Form Health Survey 12). - The two massage treatments had similar effects that were generally superior to usual care. Most notably, 36%-39% of participants receiving massage, versus only 4% receiving usual care, claimed their back pain was much better or gone. - Massage did not affect narcotic analgesic use. - Massage benefits persisted at 52 weeks for days of reduced activity, global improvement, and satisfaction.
Additional information if relevant	Five of 134 participants receiving relaxation massage and 9 of 131 participants receiving structural massage reported adverse events possibly related to massage, mostly increased pain.

Conclusions	
Key Conclusions Of Study Authors	- This study found that a course of relaxation massage, using techniques commonly taught in massage schools and widely practiced in North America, had effects similar to those of a more specialized technique, structural massage. Specifically, at weeks 10 and 26, adjusted 95% CI's did not include mean differences in improvement between massage groups large enough to be considered clinically relevant (i.e. 2-point and 1.5-point differences for the RDQ and symptom bothersomeness measures, respectively). Relaxation massage was also found more effective than usual care in improving function and decreasing pain. - Beneficial effects of both types of massage were evident immediately after the 10-week treatment period and remained statistically and clinically significant for function at the 26-week follow-up. The one-year benefits of massage were of questionable clinical significance. - These results indicate that both relaxation and structural massage are reasonable treatment options for persons with chronic low back pain. Possible advantages of relaxation massage are that it is more readily accessible because it is based on techniques taught in virtually all massage schools and is slightly less expensive than more specialized forms of massage which require additional training. - Both relaxation and structural massage had very low rates of adverse effects. - The mechanisms explaining the beneficial effects of relaxation and structural massage remain unclear. - Future research should explore the relative contributions of non-specific context effects and specific treatment effects on patient outcomes, whether different forms of massage produce benefits through the same or through different physiological pathways, whether less experienced therapists would produce similar results, whether fewer treatments could have achieved equivalent outcomes, and whether education and self-care recommendations contribute to the effectiveness of massage.

Risk of bias assessment		
Domain	Risk of bias Low High Unclear	Comments
Random sequence generation *(selection bias)*	Low	Randomization, blocked on therapist, was done using a concealed and protected centrally generated variable-sized block design created by the biostatistician. One third of participants were randomized to each group.
Allocation concealment *(selection bias)*	Low	The randomization schedule was only accessible by the statistician and was concealed and protected using a centrally-generated variable-sized block design.

Blinding of participants and personnel *(performance bias)*	High	Because of the nature of the interventions, it was not possible to blind participants or physiotherapists.The lack of blinding does not prejudice the conclusions. Therapists were not blinded to type of massage they provided. Participants knew if they received massage but were blinded to type.
Blinding of outcome assessment *(detection bias)*	Low	A research assistant blinded to group allocation administered all outcome measures at follow-up.
Incomplete outcome data *(attrition bias)*	Low	Loss to follow up (no longer interested) was at 9% and included 36 participants. All participants lost to follow-up were included in the ITT analysis.
Selective outcome reporting? *(reporting bias)*	High	The trial was not registered.
Other bias		Intention to treat analysis was used.

Sponsorship if reported		
Study funding sources if reported	This trial was funded by the National Center for Complementary and Alternative Medicine (NCCAM). It was approved by NCCAM's Office of Clinical and Regulatory Affairs. NCCAM did not participate in the research.	
Possible conflicts of interest for study authors	None declared	
Notes:		

Comments by DOWC staff

- Overall both relaxation and structural massage were effective for both pain and function with benefits lasting at least 6 months, but neither was clinically superior for treating chronic low back pain.

- The findings are generalizable as the study was conducted in a large US city within a large health care system.

- At 10 weeks, 62%-65% of participants experienced clinically meaningful improvement in the massage groups. These percentages are notably excellent considering almost two thirds of the participants reached this clinical marker.

- Treatment adherence was 93% in the relaxation massage and 88% in the structural massage groups. This high rate of adherence to the massage groups demonstrates its acceptability to the majority of participants.

- Study strengths included a large sample size with adequate statistical power to detect clinically meaningful effects, comparison of two massage techniques, inclusion of a control group, having the same therapists deliver both treatments, high treatment adherence and follow-up rates, and a long-term follow-up.
- The main limitations of the study were lack of blinding of therapists and patients, the high number of treating therapists that may have confounded treatment fidelity, slight differences in exercises recommended in the two massage groups, absence of trial registration, and unequal matching of the control intervention in format and time.

Comments by DOWC staff

- Participants assigned to usual care may possibly have reported less positive outcome reports, because they received no additional treatment and may have been disappointed they did not get massage. It would have been preferable to offer the usual care control group some type of treatment matched in format and time to the massage interventions in order to eliminate these disappointment effects and also the non-specific effects of attention.

- Authors failed to include baseline outcome scores in the main results table.

- Massage is a suitable form of treatment for the majority of the population, including health care–seeking individuals, and having little risk of injury.

Assessment by DOWC staff	
Overall assessment as suitability of evidence for the guideline ☐ High quality ☒ Adequate ☐ Inadequate	This adequate quality study provides some evidence that 10 weeks of either relaxation massage or structural massage are more effective than usual care and equally effective in improving functional disability and reducing symptoms of pain in people with chronic low back pain with benefits lasting at least 6 months.
If inadequate, main reasons for recommending that the article not be cited as evidence	

Additional references if relevant
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